

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
112713-486 (ALT5604D N4)

Re Application Of: Connell, M., et al.

Serial No.  
10/695,526

Filing Date  
October 27, 2003

Examiner  
Unknown

Group Art Unit  
Unknown

Title: **METHOD AND APPARATUS FOR KIDNEY DIALYSIS**

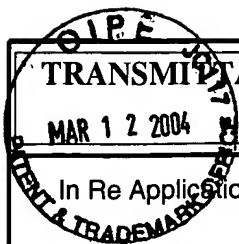
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P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).



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**METHOD AND APPARATUS FOR KIDNEY DIALYSIS**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818**  
as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

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I certify that this document and fee is being deposited on **March 9, 2004** with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
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Dated: **March 9, 2004**

\_\_\_\_\_  
Signature

**Robert M. Barrett (Reg. No. 30,142)**  
**Bell, Boyd & Lloyd LLC**  
**P.O. Box 1135**  
**Chicago, Illinois 60690-1135**  
**Tel: 312/807-4204**  
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CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Connell, M., et al.  
Appl. No.: 10/695,526  
Conf. No.: Unknown  
Filed: October 27, 2003  
Title: METHOD AND APPARATUS FOR KIDNEY DIALYSIS  
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, copies of which can be found in the parent, application no. 09/711,420, filed on November 13, 2000, be made during the course of examination of the above-identified application for United States patent, except for the following additional documents: GB 2 110 564 A, claims of pending U.S. Patent Applications 10/461,322, 10/461,237, 10/461,272.

U.S. PATENT DOCUMENTS

<u>Document No.</u>	<u>Date</u>	<u>Inventor</u>
3,563,381	2/16/71	Edelson et al.
3,946,731	3/30/76	Lichtenstein
3,992,301	11/16/76	Shippey et al.
4,096,059	6/20/78	Pinkerton
4,098,274	7/4/78	Ebling et al.
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4,370,983	2/1/83	Lichtenstein
4,477,342	10/16/84	Allan et al.
4,508,622	4/2/85	Polaschegg et al.
4,601,830	7/22/86	Chen
4,614,590	9/30/86	Rath et al.

4,618,343	10/21/86	Polaschegg
4,715,959	12/19/87	Allan et al.
4,718,022	1/5/88	Cochran
4,739,492	4/19/88	Cochran
4,747,950	5/31/88	Guinn
4,756,706	7/12/88	Kerns et al.
4,769,134	9/6/88	Allan et al.
4,770,769	9/13/88	Schael
4,804,950	2/14/89	Moon et al.
4,828,543	5/9/89	Weiss et al.
4,834,888	5/30/89	Polaschegg
4,873,623	10/10/89	Lane et al.
4,895,657	1/23/90	Polaschegg
4,898,578	2/6/90	Rubalcaba, Jr.
4,914,624	4/3/90	Dunthorn
4,916,441	4/10/90	Gombrich
4,935,125	6/19/90	Era et al.
4,971,700	11/90	Tsuji et al.
4,974,599	12/4/90	Suzuki
4,990,258	2/5/91	Bjare et al.
4,997,570	3/15/91	Polaschegg
5,024,756	6/18/91	Sternby
5,056,059	10/8/91	Tivig et al.
5,069,668	12/3/91	Boydman
5,100,554	3/31/92	Polaschegg
5,111,683	5/12/92	Fond
5,247,434	9/21/93	Peterson et al.
5,326,476	7/5/94	Grogan et al.
5,344,392	9/6/94	Senninger
5,486,286	1/23/96	Peterson et al.
5,744,027	4/28/98	Connell et al.
6,284,131	9/4/01	Hogard et al.

# **FOREIGN PATENT DOCUMENTS**

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
2 513 884	10/6/82	France

2 110 564 A	06/22/83	Europe
0 089 003	9/21/83	Europe
0 186 973	7/9/86	Europe
0 298 587	5/11/87	Europe
0 240 101	10/7/87	Europe
0 267 664	5/18/88	Europe
2 205 669	12/14/88	United Kingdom
0 311 709	4/19/89	Europe
WO 90/14850	12/13/90	PCT

### **OTHER DOCUMENTS**

Operator's Manual for SPS 550, Published by Baxter Healthcare Corp., 1987.

Operator's Instructions for A2008 Hemodialysis System, Published by Fresenius, pp 1-116.

HD-secura Dialysis Unit Operating Manual, Published by B. Braun Melsunden AG, January 1991, pp. 1-157.

Lamberti et al, "A Digital Computer Model for Optimal Programming of Hemodialytic Treatment," The International Journal of Artificial Organs, Vol. 11, no. 4, 1988, pp. 235-242.

Nephrology Dialysis Transplantation, Vol. 2, No. 2, 1987.

Monitral-S Dialysis System Brochure, January 1988, Vol. 1, No. 1.

Nephrology Dialysis Transplantation, Vol. 3, No. 4, 1988.

Zucchelli, et al., Treatment and Monitoring of Renal Patients, Nephrology Dialysis Transplantation, Symposium 27-29, April 1989 at Bologna, Italy.

Nephrology Dialysis Transplantation, Vol. 4, No. 12, 1989

COBE Laboratories Centrysystem 3 Dialysis Management System Brochure, 1989.

Gambro AB, More Care in Renal Care, AK 100 Brochure.

Gambro AB, AK 100 Ultra One Step Above Brochure.

Gambro AB, Haemodialysis Equipment Brochure, December 1990, Evaluation No. 47.

Fresenius, The A 2008 D Dialysis System Brochure.

Appl. No. 10/695,526

Fresenius, A 2008 B Dialysis System Brochure.

Baxter Healthcare Corporation, The Baxter 1550 Hemodialysis Machine Brochure, 1991.

Hospal Integra, The Hospal Vision of the Future in Dialysis Monitoring Brochure.

Hanna, Annetta, 1991 Annual Design Review, Introduction.

Althin CD Medical, Inc.; reprint of: Winning Design for Althin's System 1000; June 12 issue of Clinica.

International Design Prize of the State of Baden-Wurttemberg brochure; 1993.

Fresenius, 4008 Profile Display, Na/UF Graphics Brochure.

Fresenius, 4008 E Dialysis System Brochure.

Fresenius, 2008 H Dialysis System Brochure.

Fresenius, The Highest Standards in Hemodialysis Brochure.

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Einspruch gegen ein europäisches Patent (6 pages).

CMS 08 Handbook dated August 4, 1988, published by Fresenius AG.

Computer Modelling System 08, CMS 08 document, published by Fresenius AG.

Dialysis System A2008 C document published by Fresenius AG.

Perrone, B., et al., "Evidence of Fluid Shifts during Dialysis Sessions with Sodium and Ultrafiltration Profiles," Improvements in Dialysis Therapy, Contrib Nephrology, vol. 74, 1989, (pp. 191-199).

Erben, J. et al., "Computer-Supported Risk Analysis of Haemodialysis Patients in Combination with Possible Therapies by the CMS 08," Improvements in Dialysis Therapy, 1989, Vol. 74, page 165.

Stefoni, S. et al., "The CMS 08 Modulated Dialysis," Improvements in Dialysis Therapy, 1989, Vol. 74, page 221.

Deuber, H.J. et al., "Clinical Application of the Sodium Modelling Computation with CMS 08," Improvements in Dialysis Therapy, 1989, Vol. 74, page 159.

Eidesstattliche Versicherung (Solemn Declaration) for Raimond Walter dated January 2, 2001 (with translation).

Copy of photograph labeled Anlage 8.

Programme for European Renal Association XXIXth Congress, 5 pages.

Copy of photograph labeled Anlage 10.

Copy of photograph labeled Anlage 11.

Eidesstattliche Versicherung (Solemn Declaration) for Reiner Spickermann dated December 27, 2000 (with translation).

Claims of Pending U.S. Patent Application No. 10/461,322

Claims of Pending U.S. Patent Application No. 10/461,237

Claims of Pending U.S. Patent Application No. 10/461,272

Foreign FR 2 513 884 and WO 90/14850 listed above are not in the English language. GB 2 110 564 A corresponding to FR 2 513 884 is included in this submission. WO 90/14850 has an English abstract within the reference.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

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**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
(Use several sheets if necessary)

PTO Form 1449

Atty Docket No.  
112713-486

Application No.  
10/695,526

Applicant  
Connell, M., et al.

Filing Date  
October 27, 2003

Group  
Unknown

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
	3,563,381	2/16/71	Edelson et al.			
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	4,747,950	5/31/88	Guinn			
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	4,971,700	11/90	Tsuji et al.			
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	Gambro AB, Haemodialysis Equipment Brochure, December 1990, Evaluation No. 47.
	Fresenius, The A 2008 D Dialysis System Brochure.
	Fresenius, A 2008 B Dialysis System Brochure.
	Baxter Healthcare Corporation, The Baxter 1550 Hemodialysis Machine Brochure, 1991.
	Hospal Integra, The Hospal Vision of the Future in Dialysis Monitoring Brochure.
	Hanna, Annetta, 1991 Annual Design Review, Introduction.
	Althin CD Medical, Inc.; reprint of: Winning Design for Althin's System 1000; June 12 issue of Clinica.
	International Design Prize of the State of Baden-Wurtemberg brochure; 1993.
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